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April 20, 1999

William K. Hubbard
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Mr. Hubbard:

I am writing to protest a petition submitted to FDA proposing to ban the sale of live, raw shellfish, particularly oysters (Docket 98P0504). I understand the intent is to prevent infecting consumers with a specific bacteria that can be dangerous, even fatal. Unfortunately, the petition fails to zero in on that one bacteria (found in shellfish harvested in the Gulf of Mexico), and instead includes all nonfatal bacteria similar to it. The result of the ban would literally wipe out the Pacific Northwest shellfish industry -- not because people were in jeopardy -- but because the ban would outlaw the sale of raw shellfish that are not even infected with the bacteria (it's not even found in the Pacific Northwest).

I encourage you instead to allow the scientific community to develop a policy based on reality, not regulatory convenience. When the E-coli bacteria became a source of concern for the public, the FDA rightfully understood how absurd it would be to require that the only meat sold to consumers be fully cooked prior to sale, EVEN IF people insist on eating their meat rare. Here the same perspective applies. Rather than outlawing the sale of raw shellfish, educate the public on proper preparation techniques, and caution them about consuming raw shellfish harvested during the warmer months. The Pacific Northwest shellfish industry has always been cautious about the safety of their customers, going so far as withholding their product during the summer months to protect people from the lesser bacterial strain, *Vibrio parahaemolyticus*. Give us credit for being adults about this and allow the experts to develop a plan and a policy that protects without doing even more harm.

I apologize for the late date in commenting on this concern. It was only brought to my attention this morning when it was covered by our local newspaper, The Daily Olympian.

If you have any questions, I welcome your call. I can be reached at (360) 923-9475.

Sincerely,


Leslie S. Demich

98P-0504

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